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10/817,125	04/02/2004	Nabil L. Muhanna	M112 1140.1	1507

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WOMBLE CARLYLE SANDRIDGE & RICE
P.O. Box 7037
Atlanta, GA 30357-0037

EXAMINER

SWIGER III, JAMES L

ART UNIT	PAPER NUMBER
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3733

DATE MAILED: 07/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/817,125

Applicant(s)

MUHANNA ET AL.

Examiner

James L. Swiger

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 30-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 10-28 is/are rejected.
- 7) ☒ Claim(s) 9 and 29 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 4/24/2006 have been fully considered but they are not persuasive.

In response to applicant's argument that Tatar '142 has a recess in the head of the pedicle screw enabling a tool access to the head of the screw and also that the screw (100) can polyaxially rotate in the body (12) and that the device does not *disclose a screw having a channel that receives a ball collet*, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

The claim itself requires spaced-apart threaded posts that form a channel. The ball collet requires a *generally* spherical body. Further, the device is considered as a whole shown in Figure 5, not by the intended use of the individual parts. If the screw may functionally rotate while seated in the screw base, the collet may still exist in place, meeting the claim limitation.

For the above reasons, the following and previous rejections still apply below:

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5-6, 8, 18 and 23-24 are rejected under 35 U.S.C. 102(b) as being

anticipated by Tatar (U.S. Patent No. 5,910,142). Tatar discloses a device having a pedicle screw (100), and a pair of spaced-apart threaded posts (125a and 125b), that may be defined as a yoke since it harness or the components of the device. The threaded posts define a channel (122), a ball collet (Fig. 3) that is insertable into the channel, a rod (150) having first and second ends, wherein the first end is capable of being inserted into the ball collet bore (See fig. 5), a threaded cap (140) configured and dimensioned to mate with the threaded posts and that which provides a compressive force on the ball collet (see lines 14-15 of the abstract). The device disclosed by Tatar is also capable of being adjusted in a disassembled state, but in the assembled state (see Fig. 5) the ball collet (130) is seated in the channel (126) which may be considered concave. The rod also goes through the bore of the collet and the cap (140) is screw-coupled to the posts (125a and 125b), which have threads on the inner surfaces (124).

With further regards to claims 23-24 from above, Tatar '142 discloses the claimed invention except for a one-piece pedicle screw made of titanium. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct a device made from a biocompatible material such as titanium or a related alloy, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Claims 27 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Griss (U.S. Patent No. 5,536,268). Griss discloses a device having a one-piece pedicle screw (Fig. 2) formed from titanium (Col. 6, lines 55-59), has a threaded insertion

portion (see inside edge of Fig. 2) which is connected to what may be considered a yoke portion (66) that comprises a pair of spaced-apart posts (16-17), forming a substantially cylindrical channel (18), forming a concave seat with a cylindrical contour (22). Griss also discloses a device capable of being a spherical ball collet (Fig. 9) that can be positioned in the concave seat (Fig. 8).

Claim Rejections - 35 USC § 103

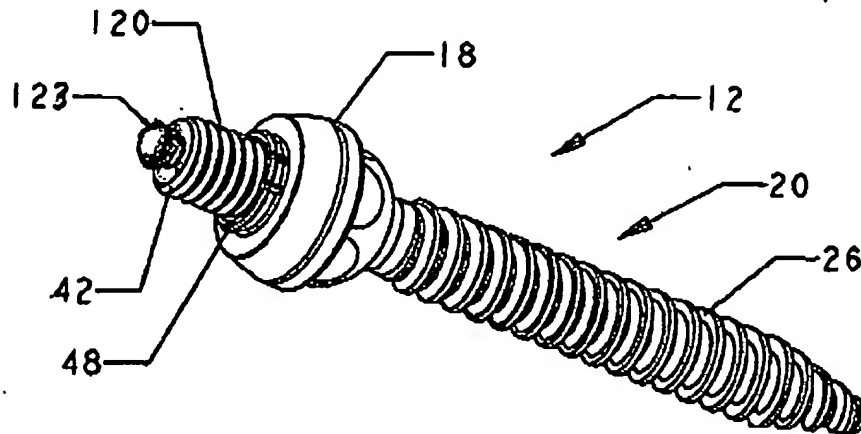
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tatar '142, in view of Doubler et al. (U.S. PG-PUB 2005/0070899 A1). Tatar discloses the claimed invention except for a crown having a cylindrical skirt and a radially inwardly projecting flange. Doubler et al. '899 discloses a crown with a cylindrical skirt and flange (see Figure X below) that enables the user to engage the outer spherical surface of the pedicle screw (par 0066) while this skirt rests on the inwardly projecting flange to more evenly distribute force throughout the connection (see bottom of par. 0075). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Tatar having at least the crown and skirt and

inwardly projecting flange in view of Doubler et al. to better enable the surgeon to better secure the rods in the place after adjusting during the surgical procedure.

Fig. 4



Claims 4 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tatar '142 in view of Brace et al. (U.S. Patent No. 6,187,005). Tatar discloses the claimed invention except for a contacting lower surface with spherical contour and a ball collet with a plurality of slots that contact the outer surface of the ball collet. Brace et al. however, discloses a spherical lower contacting surface (See Fig. 2, 40) as well as a ball collet (100) with a plurality of slots (104 et al.). The spherical bottom surface allows for a better fit of the fastener (the collet surface) permitting the device to have secure, yet flexible movement when being arranged [Col. 3, lines 35-40], while the slots allow the ball clamp (collet) to be compressed on the rod [Col. 5; lines 8-15]. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Tatar having at least a spherical lower surface and a ball clamp (collet) with slits in view of Brace et al. to better secure the pedicle screw in the

assembled state.

Claims 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tatar '142 in view of Ferree (U.S. Patent No. 6,802,844). Tatar discloses the claimed invention except for a partial hemispherical ball member having a diameter similar to the ball collet with a conical surface on the outboard side, with a centrally located protrusion and a centrally located recess. Ferree discloses a partially hemispherical ball member (see Fig. 3-H below), that is capable of having a diameter appropriate to fitting inside the collet member, a conical surface (see Fig. 3-H below), and a protrusion and recess (see Fig. 3-H below).

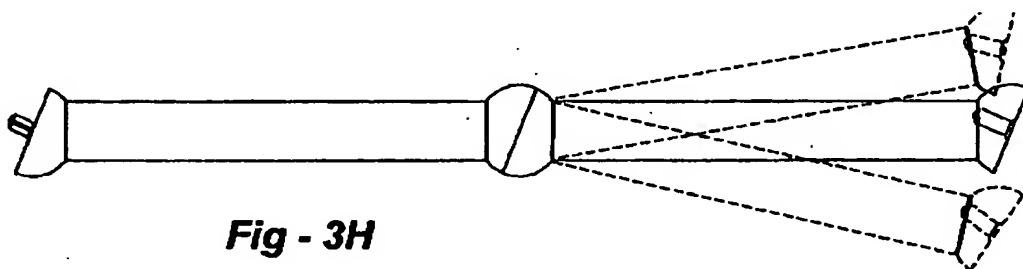


Fig - 3H

All of the above modifications to the device, according to Ferree allow for the rods to be oriented at different angles prior to tightening (Col. 8, lines 35-40). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Tatar having at least a partially hemispherical ball member with a conical surface and a protrusion and recess in view of Ferree the rods to be oriented and angled prior to fixation of the joints.

Claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tatar '142 in view of Gearin (U.S. Patent No. 3,530,548). Tatar discloses the claimed invention except for a rod that has a bulbous, spherical member at the second end.

Gearing discloses a rod that has a spherical member at the second end (18) that allows for the extensions (capable equivalents of the rods in the claimed invention) to be maneuverable in their sockets to a desired arrangement before being secured (See Col. 3). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Tatar having at least a rod having a spherical ball in view of Gearin to enable one end of the rod to be slid into place (in the claimed invention a ball collet) while the other can be directly secured into the pedicle screw device, while allowing for adjustment.

Claims 17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tatar '142 in view of Gearin '548. Tatar discloses a device having a pedicle screw (100), a pair of spaced-apart threaded posts (125a and 125b) that define a channel (122), a ball collet (Fig. 3) that is insertable into the channel, a rod (150) having first and second ends, wherein the first end is capable of being inserted into the ball collet bore (See fig. 5), a threaded cap (140) configured and dimensioned to mate with the threaded posts. The device disclosed by Tatar is also capable of being adjusted in a disassembled state, but in the assembled state (see Fig. 5) the ball collet (130) is seated in the channel (126) which may be considered concave, the rod goes through the bore of the collet and the cap (140) is screw-coupled to the posts (125a and 125b), which have threads on the inner surfaces (124).

Tatar does not disclose, however, a rod that has a bulbous, spherical member at the second end. Gearin discloses a rod that has a spherical member at the second end

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(18) that allows for the extensions (capable equivalents of the rods in the claimed invention) to be maneuverable in their sockets to a desired arrangement before being secured (See Col. Three). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Tatar having at least a rod having a spherical ball in view of Gearin to enable one end of the rod to be slid into place (in the claimed invention a ball collet) while the other can be directly secured into the pedicle screw device, while allowing for adjustment.

Further, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the assembly of Tatar in view of Gearin having a plurality of pedicle screw assemblies including a first and second pedicle screws and first and second threaded caps since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Claims 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tatar '142 in view of Ferree '844. Tatar discloses the claimed invention except for a contacting lower surface with spherical contour and a ball collet with a plurality of slots that contact the outer surface of the ball collet. Brace et al. however, discloses a spherical lower contacting surface (See Fig. 2, 40) as well as a ball collet (100) with a plurality of slots (104 et al.). The spherical bottom surface allows for a better fit of the fastener (the collet surface) permitting the device to have secure, yet flexible movement when being arranged [Col. 3, lines 35-40], while the slots allow the ball clamp (collet) to

be compressed on the rod [Col. 5, lines 8-15]. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Tatar having at least a spherical lower surface and a ball clamp (collet) with slits in view of Brace et al. to better secure the pedicle screw in the assembled state.

Tatar discloses the claimed invention except for a partial hemispherical ball member having a diameter similar to the ball collet with a conical surface on the outboard side, with a centrally located protrusion and a centrally located recess. Ferree discloses a partially hemispherical ball member (see Fig. 3-H *above*), that is capable of having a diameter appropriate to fitting inside the collet member, a conical surface (see Fig. 3-H *above*), and a protrusion and recess (see Fig. 3-H *above*).

All of the above modifications to the device, according to Ferree, allow for the rods to be oriented at different angles prior to tightening (Col. 8, lines 35-40). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Tatar having at least a partially hemispherical ball member with a conical surface and a protrusion and recess in view of Ferree so that the rods can be oriented and angled prior to fixation of the joints.

Further, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the assembly of Tatar having a plurality of pedicle screws, first and second ball collets, a first and second rod and first, second and third caps, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Claims 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tatar '142 in view of Ferree '844. Tatar discloses a device having a pedicle screw (100), a pair of spaced-apart threaded posts (125a and 125b) that define a channel (122), a ball collet (Fig. 3) that is insertable into the channel, a rod (150) having first and second ends, wherein the first end is capable of being inserted into the ball collet bore (See fig. 5), a threaded cap (140) configured and dimensioned to mate with the threaded posts. The device disclosed by Tatar is also capable of being adjusted in a disassembled state, but in the assembled state (see Fig. 5) the ball collet (130) is seated in the channel (126) which may be considered concave, the rod that goes through the bore of the collet and the cap (140) is screw-coupled to the posts (125a and 125b), which have threads on the inner surfaces (124).

Tatar discloses the claimed invention except for a partial hemispherical ball member having a diameter similar to the ball collet with a conical surface on the outboard side, with a centrally located protrusion and a centrally located recess. Ferree discloses a partially hemispherical ball member (see Fig. 3-H *above*), that is capable of having a diameter appropriate to fitting inside the collet member, a conical surface (see Fig. 3-H *above*), and a protrusion and recess (see Fig. 3-H *above*).

All of the above modifications to the device, according to Ferree allow for the rods to be oriented at different angles prior to tightening (Col. 8, lines 35-40). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Tatar having at least a partially hemispherical ball member with a conical surface and a protrusion and recess in view of Ferree the rods to

be oriented and angled prior to fixation of the joints.

Further, with regards to claims 25-26, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the assembly of Tatar '142 having a plurality of rods and partial hemispherical balls, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Allowable Subject Matter

Claims 9 and 29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion


THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Swiger whose telephone number is 571-272-5557. The examiner can normally be reached on Monday through Friday, 9:00am to 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

 7/10/06

JLS



CORRINE McDERMOTT
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700